

from about 0.1 to about 9, and the mean molecular weight of the mixed polymer is greater than about 350 250 kD.

56. (Previously added) A process according to Claim 29 wherein the algae material used in the process is brown algae.

REMARKS AND ARGUMENTS

A. Claim Status

Claims 29-42, 52, and 56 are pending in the application.

Claims 29-42, 52, and 56 were rejected under 35 U.S.C. § 112, first paragraph (written description).

Claims 29-42, 52, and 56 were rejected under 35 U.S.C. § 112, second paragraph (definiteness).

Claims 29-42, 52, and 56 were rejected under 35 U.S.C. § 103 (a).

Claim 52 was rejected under 35 U.S.C. § 102 (b).

B. Amendments

Claims 29 and 52 have been amended.

C. Interview

On July 29, 2003, a telephone interview was conducted with Examiner and Applicants' Agents to discuss the instant Final Office Action. In particular, the discussion addressed the art of processing algae material; and some of the differences between the commercial alginate and commercial alginate purification processes of the prior art, and the algae material and purification process of the instant invention.

D. Arguments

1. Rejections based on 35 U.S.C. § 112, first paragraph (written description)

Claims 29-42, 52, and 56 were rejected under 35 U.S.C. § 112, first paragraph. (written description). Applicants respectfully traverse this rejection, as it appears to be based on

misapprehensions about the scope and meaning of the claims, the specification, as well as the understanding of those in the art regarding algae processing and alginate purification. In particular, the instant rejection appears to be based on the misapprehension of the words "suspension," "solution," and "extracting" (or "extraction"), all of which are used in the specification and claims in accordance with their plain and ordinary meaning.

It is respectfully suggested that one of ordinary skill and familiar with the art would understand that the alginate is being extracted into solution from the algae material.

Regardless, Claim 29 has been amended to address the examiner's concerns. No new matter has been introduced by this amendment, nor has the scope of the claims been narrowed. Support for this amendment may be found throughout the specification, *inter alia*, at p. 13, last line through p. 14, second paragraph; page 7, fourth paragraph through page 8, second paragraph. p. 7, third paragraph; p. 4, last paragraph, first sentence; p. 3, last paragraph, continuing to page 4; p. 1 second paragraph, especially the last sentence, p. 5, second paragraph through p. 7, second paragraph.

For example, at page 14, first paragraph, it is made clear that after the complex-forming agent (EDTA in this example) is added, the solid matter is allowed to settle, the supernatant is decanted off, and the supernatant is then filtered through a series filters of decreasing pore sizes, with the last pore size being 0.1 μm . With a pore size this small, the liquid passing through the filter - the filtrate - would be understood by those of ordinary skill in the art to be a solution containing dissolved alginate.

The next paragraph then begins with the statement "The addition of salt to the filtrate then follows." This and the following paragraphs through p. 16, second paragraph, convey to one of ordinary skill that the subsequent processing is done with the filtrate - that is to say a now filtered solution.

Additionally, applicants respectfully submit that those of ordinary skill in the art, reading the application, would understand that when a complex-forming agent such as EDTA is added to alginate, the complex-forming agent removes multivalent cations from the algae material, which

are then replaced in the algae material by monovalent cations. The resulting alginate, containing monovalent cations, is water-soluble.

Finally, the examiner has correctly noted that Claim 52 contains a typographical error, and incorrectly recites the value of 350 kD. This has been amended to recite a mean molecular weight of the mixed polymer greater than about 250 kD. This amendment is supported in the specification at p. 9, line 15; again, no new matter has been introduced.

All of the reasons for the written description requirement rejections having been addressed or rendered moot, applicants respectfully request that these rejections be withdrawn.

2. Rejections based on 35 U.S.C. § 112, second paragraph (definiteness)

Claims 29-42, 52, and 56 were rejected under 35 U.S.C. § 112, second paragraph, based on the phrase “extracting an algae material... for providing a solution containing solved alginate...” Applicants respectfully traverse this rejection as above, and submit that claim 29 as amended further alleviates any concerns regarding alleged indefiniteness. Therefore, Applicants respectfully request that this rejection be withdrawn.

3. Rejections based on 35 U.S.C. § 103.

Claims 29-42, 52 and 56 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zimmermann et. al. (DE 42 04 012 A1) or Klöck et. al. (AP). Applicants respectfully traverse these rejections. As noted above, this rejection was based on the misapprehension that claim 29 as drafted could be read to include the purification of stably solid alginate by dissolution of contaminant solid matter, i.e. the acid treatment of chemically modified alginate beads as disclosed in these references.

As recited in claim 29, the starting material is a raw algae material. Treatment with a complex forming agent causes some of the alginate to dissolve, and impurities remain in the solid matter. (See current specification, p. 7, third paragraph; p. 4, last paragraph, first sentence; p. 3, last paragraph, continuing to page 4; p. 1 second paragraph, especially the last sentence, p. 5, second

paragraph through p. 7, second paragraph). This is antithetical to the prior art, where the contaminants are dissolved to leave solid alginate

In particular, one of ordinary skill in the art could not have been motivated by anything in the Zimmerman & Klöck references to purify algae material using a complex forming agent, as these references relate to the acid washing/chemical treatment of solid alginate beads to degrade the contaminants into the then discarded solution. In these references, commercial alginate is first precipitated into solid beads with barium chloride. To purify this solid alginate, it is incubated with a strong acid solution at a high temperature. According to the reference, the acids dissolve the contaminants, purifying the alginate.

For example, the Klöck reference teaches that “the contaminants were eluted by treatment of [the] Ba²⁺ [alginate] beads using different reagents followed by ethanol extraction.” (Klöck, p. 640, first column, lns. 16-25). In particular, the alginate beads are suspended in “4.5 [liters] of 1 N acetic acid” and incubated for 14 hours to remove impurities. (Id., lns. 26-34). These alginate beads are not dissolved until the barium is removed, and EDTA is used only in this final recovery step, to dissolve and recover the alginate from the by then acid purified, solid barium alginate. (Id., lns. 45-52.)

In sum, these references teach that alginate purity is improved when contaminants are dissolved in acid while the alginate remains solid. In contrast, the present invention contradicts this teaching: the alginate is dissolved while the contaminants remain in the solid and are removed by filtration. Since there is nothing in the references to motivate one of ordinary skill in the art to try the process of the present invention, Applicants respectfully request that this rejection be withdrawn and the claims allowed.

4. Rejection based on 35 U.S.C. § 102 (b).

Claim 52 was rejected under 35 U.S.C. § 102 (b) as being anticipated by Balz et. al. (US 5,132,295), based on the assumption that the alginates of Balz would inherently have the same composition of the present invention. Applicants respectfully traverse this rejection.

Claim 52 is a product-by-process claim, and the product alginate is produced by a completely different process than the alginate produced in Balz. For example, in Balz the alginate is put into solution using a strong base, sodium hydroxide, and no complex-forming agent is used. Further, it is then precipitated using calcium ions, which it should be noted, can be incorporated into the alginate. See, e.g. Klöck et. al, p. 639, last paragraph. The precipitate is then subjected to highly acidic conditions. Given these differences, the alginate of the Balz reference cannot be assumed to necessarily have the same inherent properties as the alginate of claim 52. Applicants respectfully request that this rejection be withdrawn.

5. Response to Advisory Action

a. First and third paragraphs

The examiner states: "The claim limitation 'raw alginate material' (line 3 of claim 29) raises new issues for consideration, in particular, under 35 U.S.C. 112, second paragraph. Algae material being raw and not raw is relative and subjective, and it would be uncertain as to the form of algae material that is raw and not raw within the scope of the claims. It is unclear from the specification as to when during processing of algae material the algae material is converted from a raw algae material into a non-raw algae material." The applicants respectfully traverse.

It is respectfully suggested that one of ordinary skill in this art will recognize that the terms "raw algae material" and "highly-purified alginate composition" as used in amended Claim 29 represent source material and end product respectively. One of ordinary skill in this art will also recognize that "raw algae material" includes both "commercially available raw alginate" and algae obtained in its natural state. The invention is a process, which must be considered as a whole. The step of obtaining alginate in dissolved form is only one step in the process. One of ordinary skill in this art will further recognize that a crucial distinction between the end product and all of these source materials is that the end product alone possesses high biocompatibility. Applicants intend to supply affidavits and an IDS containing citations in support of these statements in a supplementary reply.

Further support is to be found in the present specification. Beginning on Page 4, the applicants make a clear distinction between "highly purified alginate," the end-product of this invention, (lines 20-28), and "commercially available raw alginate" (lines 30-34). The latter is described as "blends or mixtures of different algae materials, with the inclusion of animal or other foreign materials [which] therefore cannot in principle provide highly-purified alginate." At the same time, applicants elsewhere describe the source material as "clean, fresh algae material or dried algae material" (p.4, lns. 36-37) and material acquired "at the place of algae harvesting" (p. 5, lns. 37-38).

Both types of source material are thus clearly delineated and contrasted with the end product, "highly purified alginate."

A crucial attribute of this end product is high biocompatibility (p. 4, ln. 24), which is well established in the examples of the specification, pp. 12 - 25. Biocompatibility is a crucial distinction of the end product over all the source materials. "Alginates according to the invention are biocompatible, by contrast with conventional alginate extracts . . ." (p. 11, lns. 6-7.) One of ordinary skill in this art will recognize that "conventional alginate extracts" includes the previously mentioned "commercially available raw alginate." Direct comparison of the biocompatibilities of "Raw alginate" and the materials of this invention can be seen in the chart at p. 16, lines 25-36.

b. Second paragraph

The examiner states "There is no description of obtaining a solution by adding only EDTA to insoluble algae material containing multivalent cations, and these cations being replaced by monovalent cations that have not been added such as by adding sodium carbonate as described in the specification." Applicants respectfully suggest that it will be recognized by those of ordinary skill in this art that sufficient monovalent cations to dissolve the alginate may be already contained in the cell walls of algae that grow in salt water. Alternatively, monovalent cations may be added without departing from the scope of the present invention. The present invention is a process, which must be considered as a whole. The step of obtaining alginate in dissolved form is only one step in the process.

Applicants intend to supply affidavits and an IDS containing citations in support of these statements in a supplementary reply.

c. Fourth paragraph

The present invention is patentably distinct from those of the cited Zimmermann and Klöck references. The present invention is a process, which must be considered as a whole, and a composition made with the process, which differs significantly from that of these two references.

In the references the alginates are first precipitated, then purified with acids at relatively high temperatures. It will be recognized by those of ordinary skill in this art that the alginate so treated will be physically and chemically modified with respect to the alginate in the present invention. The process of the references continues with further purification using alcohol, and finally dissolved. This process cannot be used to extract alginate directly from naturally occurring algae material.

By contrast, in the process of the present invention, the alginate is purified in a dissolved state in the beginning. It can be used to extract alginate directly from naturally-occurring algae material. No acid or heat is used, and alcohol, not acid, is used for precipitating. It will be recognized by those of ordinary skill in this art that this process is distinct from that in the references in that it involves different steps in a different order and results in a chemically and physically distinct final alginate.

Applicants intend to supply affidavits and an IDS containing citations in support of these statements in a supplementary reply.

d. Fifth paragraph

The examiner states "[T]here is inadequate evidence to establish the claimed process produces a more pure alginate and/or alginate that differs in other properties." In response, the applicants respectfully reiterate the argument of the Response to Final Office Action of August 5, 2003, in section 4, above.

E. Conclusion

Applicants believe that the foregoing amendments and remarks have overcome or rendered moot all grounds for rejection and objection, and that the application is in a condition for allowance. Applicants therefore respectfully request prompt action on the claims and allowance of the application. If the Examiner believes that personal communication will expedite prosecution of the application, the Examiner is invited to telephone Applicants' undersigned agent directly.